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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,561	04/22/2004	Mark Brister	P1315	6352

28390 7590 12/15/2004
MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

LACYK, JOHN P

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/829,561

Applicant(s)

BRISTER, MARK

Examiner

John P Lacyk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-12, 14-18 and 20-32 is/are rejected.
- 7) ☒ Claim(s) 3, 13 and 19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/22/2004</u> | 6) <input type="checkbox"/> Other: ____ |

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1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The radioactive wire, radioactive strip, radioactive pellet, radioactive stent, receptacle or lumen that contains radioactive material, receptacle or lumen that receives radioactive material, receptacle or lumen that is coated with radioactive material lacks proper antecedent basis in the specification. The specification only states that the radiation source may be guided to the treatment site and that it may be activated by withdrawing a sheath covering the radiation source or by providing a voltage to deliver x-ray radiation. It provides no proper antecedent basis to limit the radiation source only to those discussed above and does not even mention the types claimed in the specification.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-2, 4-7, 15, 27-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Phelps et al.

Phelps et al discloses a method and device for locating and treating vulnerable plaque.

Phelps et al teaches (column 2, lines 16-34) using energy or light emitters to identify the vulnerable plaque and teaches using the energy or light emitters to treat the plaque.

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The emitters may be in the microwave, ultrasound or infrared range or use a laser light (column 5, lines 20-32) of which at least the infrared is considered to be a radiation source. With regard to claim 2, since the specification as discussed above fails to specifically define or limit the limitations, the device of Phelps et al is considered to be a radioactive strip since it radiates radiation to treat the plaque. With respect to claims 4-7, it is well known in the art to use a guidewire to assist in introducing a catheter into the body, therefore these steps are considered to be an inherent part of a method of inserting a catheter into the body. Also an access site must be made in order to insert a catheter or guidewire into the vessel initially.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8-12, 14, 16-18, 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phelps et al in view of Geoffrion et al.

Geoffrion et al discloses a treatment device for treating a site within a vessel in a body. Geoffrion et al shows that it is well known to use a balloon to either center the catheter within the body or to stabilize or secure the catheter in place in the body and also shows that it is well known to use two balloons, one proximal and one distal to aid in properly positioning the treatment device. Therefore a modification of Phelps et al to include

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balloons to help properly position and secure the device in position would have been obvious in view of Geoffrion et al.

6. Claims 3, 13 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

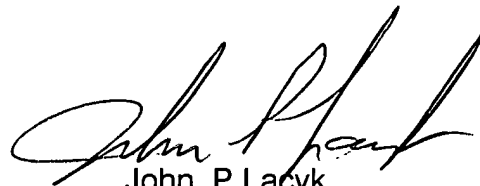
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Turnlund et al is cited to further show the use of radioactive device used to promote cell growth in a vessel that is being treated having a dose range of 1-600Gy. Tu et al and Doscher et al are cited to further show the state of the art of treating vulnerable plaque.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P Lacyk whose telephone number is 571-272-4728.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John P Lacyk
Primary Examiner
Art Unit 3736

J.P. Lacyk